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EXAMINER

KOHARSKI, CHRISTOPHER

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

09/25/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/645,764	Applicant(s) ZHOU, PU	
	Examiner CHRISTOPHER D. KOHARSKI	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06/08/2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10,12,27-30,32 and 33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10,12,27-30,32 and 33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgements

The Examiner acknowledges the reply filed 06/08/2009 in which claim 10 was amended. Currently claims 10, 12, 27-30, 32 and 33 are pending for examination in this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10, 27 and 29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Regarding claims 10, 27 and 29, the Examiner only finds support for the wire transition on page 11, ln 5-17 and page 9, lines 7-9. This support covers wires with "a gradual transition" and a "more abrupt transition", the Examiner cannot find any drawings showing the transition area. Therefore the meaning and definition of a "direct" transition lacks support within Applicant's specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 3763

Claims 10, 27 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding claims 10, 27 and 29, the claims reference a "direct" transition, this term is broad and does not have a definitive meaning and a broad and ambiguous term in the instant application. Further without any specific disclosure of the wire transition the Examiner cannot determine the meets and bounds of the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 10, 12, 27-30, and 32-33 are rejected under 35 U.S.C 103(a) as being unpatentable over Schoenholtz (USPN6,203,534) in view of Cohen (USPN5,330,521) (or Klint (US2002/0074051)).

Regarding claims 10, 12, 27-30, and 32-33, Schoenholtz discloses a catheter (12) with a braided reinforcing layer (24) that is made from two or more continuous wires woven together made up of stainless steel (col 4, ln 10-35) (Figures 1-3) with a protective overcoat (42, 22) over this woven wire reinforcement. Schoenholtz meets the claim limitations as described above except for the distal and proximal braided section having a decreasing cross sectional area.

However, Cohen teaches an electrical lead including a wire core having a cross-sectional area, which differs over its length.

Regarding claims 10, 12, and 27-30, 32-33, Cohen teaches (Figure 4) an implantable tubular device that uses a wire-reinforcement coil (42) with a diameter that decreases in a direct transition within one revolution of each wire along its length (dL, dS) along with various production methods (Figure 4, col 8, ln 60-70, col 9, ln 1-43).

At the time of the invention, it would have been obvious to add the reinforcement member teachings of Klint to the system of Schoenholtz because as taught in Klint the reduction of the core diameter of the reinforcement member allows for larger transverse flexibility and higher tip softness without comprising torque stability. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Cohen (cols 1-2).

Additionally, Klint teaches a guidewire with lengthwise diameter variability.

Regarding claims 10, 12, and 27-30, 32-33, Klint teaches (Figure 2) a tubular device that consists of a wire-reinforcement coil (7,8,9) comprising 2-8 helical wound

Art Unit: 3763

wires with a diameter that directly decreases along its length (15, 13, 11) with each wire revolution.

At the time of the invention, it would have been obvious to add the reinforcement member teachings of Cohen to the system of Schoenholtz because as taught in Cohen the reduction of the core diameter of the reinforcement member allows for tip flexibility and tracking within a patient without overly compromising the tip strength. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Klint ([0001-0022]).

The modified Schoenholtz meets the claim limitations as described above except for the specific 1.5 mm to 1.0 mm diameter sizes.

Regarding claims 10, 12, and 27-30, 32-33, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the braid diameters as claimed by Applicant since Cohen that other varied diameters depending on the particular application may be employed (col 9, ln 10-25) and Klint discloses several varied diameters depending on the application of the medical device, and since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Response to Arguments

Applicant's arguments filed 06/08/2009 have been fully considered but they are not persuasive. Applicant's Representative asserts that the claim rejections under 112 are improper and that one of ordinary skill in the art would understand the transition

Art Unit: 3763

terms and "directly transitioning". Applicant's Representative asserts that the combination of references of Schoenholtz (USPN6,203,534) in view of Cohen (USPN5,330,521) (or Klint (US2002/0074051) does not meet the claim limitations and do not disclose "...the continuous wires of the reinforcing braid layer transitions directly from the distal diameter of each of the continuous wires..." and "...the transition occurring in less than one revolution of the wire..."

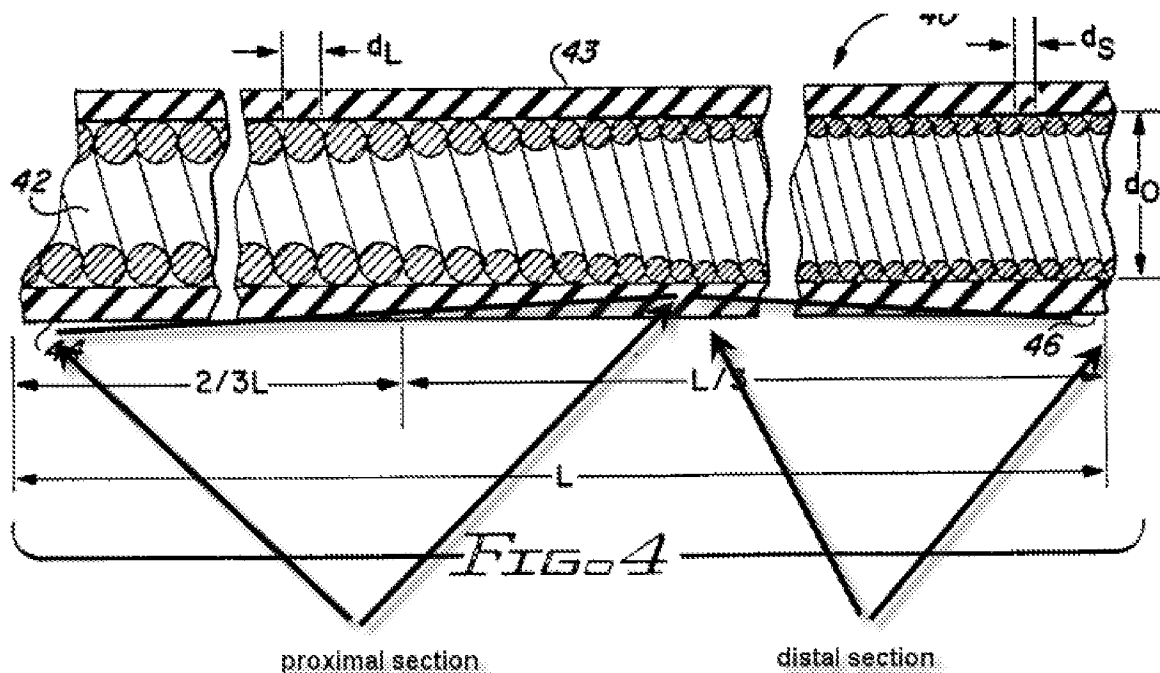
The Examiner has fully considered Applicant's arguments but they are not persuasive. It is examiners position that given a careful reading, the claims do not distinguish over the prior art of record.

Regarding the 112 rejections of the claims, the Examiner asserts the rejection is proper. Applicant's Representative has not submitted any evidence from the instant application that supports or discloses a definition of the term "directly". The Application's disclosure lacks any drawings (most representative is Figure 5, but lacks critical transitional wire area) of the transition point and the specification does not describe "a direct transition" with any specific definition.

The Examiner asserts that the combination of Schoenholtz (USPN6,203,534) in view of Cohen (USPN5,330,521) (or Klint (US2002/0074051) discloses a "direct transition" between the wire diameters. The Cohen references shows a wire core that tapers over its length, the Examiner considers this a direct transition over to a different diameter; the Klint reference shows a guidewire core that is ground down to decrease over its length and again is considered to directly transition to a different diameter. During patent examination, the claims are given the broadest reasonable

Art Unit: 3763

interpretation consistent with the specification. See *In re Morris*, 127 F.3d 1048, 44 USPQ2d 1023 (Fed. Cir. 1997). See MPEP §2111 - §2116.01 for case law pertinent to claim analysis. The meaning of "directly" lacking any specific definition set forth within Applicant's disclosure is "to turn, move, change, show or point the way for, extend or project along a specified line." Therefore the Examiner considers the tapered cores of Cohen and Klint to be directly transitioning along their lengths. Regarding the transition occurring in less than revolution of the wire, the Examiner asserts that each of



the references discloses the transition sections of the proximal section and the distal section occurring in less than a single revolution of the wire around the catheter (see above). Since Applicant's claims of the distal and proximal sections are broad, several different interpretations of the sections can be used to supply a single transition as shown above.

The prior art of record teaches all elements as claimed and these elements satisfy all structural, functional, operational, and spatial limitations currently in the claims. Therefore the standing rejections are proper and maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 5:30am to 2:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3763

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 9/21/2009

/Christopher D Koharski/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763